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FOOD AND DRUG ADMINISTRATION
CHICAGO DISTRICT
300 S. RIVERSIDE PLAZA
SUITE 550 SOUTH
CHICAGO, ILLINOIS 60606

November 16, 1999

WARNING LETTER
CHI-1-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Stephen D. Rubin, President
Vita Food Products, Inc.
2222 W. Lake St.
Chicago, IL 60612

Dear Mr. Rubin:

On April 27, 30 and May 5, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant as a follow-up to our inspection in May 1998, and subsequent letter dated July 10, 1998, identifying certain deficiencies. The inspection covered the new FDA Hazard Analysis Critical Control Point (HACCP) regulations. This FDA inspection was made to evaluate HACCP requirements. At the conclusion of the inspection, you were presented with FDA-483, List of Observations, and Form FD-3501, Domestic Seafood HACCP Report. The forms describe deviations from FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for Human Food (21 CFR 110). By virtue of these violations, the cold smoked salmon and herring products processed at your facility at 163 N. Aberdeen, Chicago, Illinois, are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigators found the following continued violations:

- Your firm has not met the requirements of 21 CFR 123.6(b) to have a HACCP plan for the control of *Clostridium botulinum* and metal fragments, hazards which are reasonably likely to occur, in your vacuum-packaged pickled herring and herring in wine sauce. In order to comply with 21 CFR123.6(c), your plan must list all the necessary critical control points and critical limits that must be met to reduce these hazards to a reasonable level.

  FDA's Fish & Fisheries Products Hazards & Control Guide, second edition, lists four acceptable methods of controlling *C. botulinum* in pickled fish:

  1. Adding sufficient salt to produce a water phase salt of 5% or greater in the loin muscle.

  2. Acidifying the loin muscle to a pH of 5.0 or below.

  3. Reducing the water activity of the loin muscle to 0.97.

  4. Making a combination of salt, pH, and/or water activity adjustments that prevent the growth of *C. botulinum*. This must be established by scientific study.

- Your firm has not met the requirements of 21 CFR 123.8 to verify that your HACCP plan for cold-smoked salmon is adequate for the control of *C. botulinum,* e.g., you do not have scientific data which demonstrate that your critical limits of 3.5% water phase salt or 3.0% water phase salt in conjunction with a minimum of 100 ppm nitrites are achieved in the final product. It will be necessary to correct the following inadequacies in your plan in order to verify your plan:

    1. Your plan has no control points at the brine injection, drying, and cold smoking steps.

    2. There are no critical limits set for several parameters which impact on the distribution and concentration of the salt in the product, e.g., belt speed, thickness of the fish, brine injection line pressure, injection time/volume, gauge and condition of needles, and penetration depth of needles.

    3. For products that rely on nitrites for control of *C. botulinum*, you have not verified that the critical limit for nitrite in the brine is adequate to achieve a final product concentration of 200 ppm.

    4. There are no critical limits for maximum product temperature at the cold-smoking step. In cold-smoking, it is important that the product does not receive so much heat that the number of spoilage organisms is reduced to the point that they no longer inhibit the growth and toxin formation of *C. botulinum.*

It is not clear from your HACCP plan whether all of the cold-smoked salmon products you make rely on nitrites. Where you use different methods for controlling *C. botulinum*, separate HACCP plans are required (21 CFR 123.6(b)).

- Your firm has not met the requirements of 21 CFR 123.7(d) to take corrective action when a critical limit was not met. Your firm did not document that a corrective action was taken in your cold-smoked salmon operation when you deviated from your critical limit of 65 degrees salimeter for brine (records for April 20, 1999 and April 21, 1999).

- You have not met the requirements of 21 CFR 123.11(b) to monitor and maintain sanitation records to document the following:

    1. Conditions and cleanliness of food contact surfaces;

    2. Prevention of cross contamination;

    3. Maintenance of hand washing and hand sanitizing facilities;

    4. Protection from adulteration;

    5. Proper labeling, storage and use of toxic compounds;

    6. Control of employee health conditions; and,

7. Exclusion of pests.

The violations cited are not all inclusive since not every product could be evaluated during the inspection. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. You should take prompt action to correct these violations. Although improvements were reported, we are concerned that no substantial corrections were made since the inspection in July 1998. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We are also providing firm's the opportunity to take a HACCP refresher course to assist in better understanding and working with the Seafood HACCP program. Please contact the local FDA office for further information. If you enroll in one of these courses we will extend your response time or further regulatory action provided products are not critically compromised resulting in a danger to health.

In addition, we determined that some of your operations are defined under the import requirements of the regulations, so we also evaluated your import program under the seafood HACCP regulations. These requirements became effective on the same date as the requirements for domestic operations and can be found in 21 CFR Section 123.12. At the conclusion of the inspection, the investigators also issued an Importer Seafood HACCP Report Form 3502. Deficiencies concerning documents for the seafood you import are covered under the Import Program are included as follows:

- You have not met the requirements of 21 CFR 123.12 that you have written verification procedures to ensure that your imported product has been processed in compliance with the requirements of 21 CFR 123. You have no specifications to ensure that the product is not adulterated when delivered for entry into the United States or affirmative steps are taken to ensure that the product conforms with the requirements of 21 CFR 123.
- You have not met the requirement of 123.12(c) to maintain records that document the performance and results of the affirmative steps taken for the salmon products you import.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention Paul Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

Raymond V. Mlecko
District Director